

201-15434A₁

HIGH PRODUCTION VOLUME (HPV)
CHEMICALS CHALLENGE PROGRAM

REVISED TEST PLAN

For

Terphenyls, Partially Hydrogenated

CAS NO. 61788-32-7

Prepared by:

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August, 2003
Revised July, 2004

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EXECUTIVE SUMMARY

Solutia Inc. voluntarily submits the following screening information data and Test Plan covering the chemical, Terphenyls, Partially Hydrogenated (CAS No. 61788-32-7), for review under the Environmental Protection Agency's High Production Volume (HPV) Chemicals Challenge Program.

A substantial amount of data exists to evaluate the potential hazards associated with Hydrogenated Terphenyls. Use of key studies or estimation models, available from data already developed, provide adequate support to characterize the Endpoints in the HPV Chemicals Challenge Program without the need for additional, unnecessary testing.

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TEST PLAN FOR PARTIALLY HYDROGENATED TERPHENYLS

I. INTRODUCTION AND IDENTIFICATION OF CHEMICAL

Under EPA's High Production Volume (HPV) Chemicals Challenge Program, Solutia Inc. has committed to voluntarily compile basic screening data on Partially Hydrogenated Terphenyls (CAS No. 61788-32-7). The data included in this Test Plan provide physicochemical properties, environmental fate, and human and environmental effects of Partially Hydrogenated Terphenyls, as defined by the Organization for Economic Cooperation and Development (OECD). The information provided comes from existing data developed on behalf of Solutia Inc. or found in the published scientific literature and fulfills Solutia's obligation to the HPV Challenge Program.

A. Structure and Nomenclature

The chemical substance identified as "Partially Hydrogenated Terphenyls", the subject of this document, is actually a "Chemical Substance of Unknown or Variable Composition, Complex Reaction Products and Biological Material (UVCB) mixture with the CAS Registry Number of 61788-32-7. As such, the substance has no recognized chemical structure. The substance is a commercial mixture of several chemical constituents which are derived from a common chemical manufacturing process. This UVCB substance is derived from the partial hydrogenation of an unspecified mixture of the ortho-, meta- and para- isomers of terphenyl, with a lesser amount of quaterphenyl isomers. There is no physical blending of any of the components in the manufacture of this UVCB substance.

Solutia's current commercial products are hydrogenated to a nominal 40% of the theoretical amount of chemical substitution. Essentially all of this UVCB substance is marketed under the commercial trade name of THERMINOL¹ ® 66 Heat Transfer Fluid. A small amount is marketed under the trade name HB-40¹® Plasticizer. Similar products with the brand names Santosol 340 and Santotherm 66 are no longer marketed.

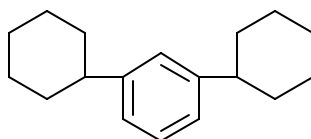
THERMINOL® 66 Heat Transfer Fluid is designated as the test article identification in many of the studies presented in this dossier; in a few cases, data from other commercial (noted above) and experimental products with similar, but slightly modified compositions, are also presented where appropriate.

¹ THERMINOL and HB-40 are registered trademarks of Solutia Inc.

Where data are developed using modeling, use of an undefined mixture as the test article is not appropriate. Consequently, the following specific chemical entity was selected as representative of the UVCB mixture. Solutia does not isolate this chemical commercially, but it is believed to be a significant component of the UVCB mixture.

Benzene, 1,3-dicyclohexyl-

$C_{18}H_{26}$



B. Manufacturing & Use

Commercial Partially Hydrogenated Terphenyls are manufactured by a single US producer, Solutia Inc. at a single US manufacturing site. The product is also manufactured by Solutia at sites in the United Kingdom and China.

The term “Partially Hydrogenated Terphenyls”, is used to describe a commercial mixture of several chemical constituents which, as manufactured by Solutia, are derived from a common chemical manufacturing process. This UVCB substance is manufactured by the partial hydrogenation of an unspecified mixture of the ortho-, meta- and para- isomers of terphenyl, with a lesser amount of quaterphenyl isomers. The composition of the product is a consequence of the reaction chemistry and is not substantially altered through the manufacturing process. There is no physical blending of any of the components to make this UVCB substance. Solutia’s current commercial products are hydrogenated to a nominal 40% of the theoretical amount of chemical substitution.

Compositions of the various commercial and developmental products used as test articles in this dossier may vary slightly due to slight differences in the composition of the feedstock that has been hydrogenated. Such differences are small enough that all studies presented can still be considered representative of Partially Hydrogenated Terphenyls, CAS Number 61788-32-7.

The majority of the Partially Hydrogenated Terphenyls manufactured today are marketed as industrial heat transfer fluids under the trade name Therminol® 66 Heat Transfer Fluid. The product is used commercially as a high temperature heat source in various

industrial processes. As such it is used in a closed system where the fluid is heated by an external source such as natural gas, then distributed through a closed piping system to one or more heat users in the industrial process. Once heat is removed from the fluid, it is recirculated back to the heat source. All heat transfer systems using Partially Hydrogenated Terphenyls are liquid systems which operate below the boiling point of the product. This ensures low operating pressure and minimizes the potential for release of vapors to the environment during routine operation.

A small amount of Partially Hydrogenated Terphenyls is also marketed as plasticizers or polymer modifiers under the trade name HB-40 Plasticizer.

A TLV of 4.9 mg/m³ (8-hr TWA) has been established for Partially Hydrogenated Terphenyls (ACGIH, 2002). This value has been established to protect against possible dermal or respiratory tract irritation. Only a few employees are involved in the manufacture of commercial Partially Hydrogenated Terphenyls. There is minimal potential for skin or airborne exposure due to the closed nature of the manufacturing process. Eye and skin protection are routinely worn, and respiratory protective equipment is available should airborne exposure limits be exceeded.

II. TEST PLAN RATIONALE

The information obtained and included to support this Revised Test Plan has come from either 1) internal studies conducted by/or for Solutia Inc. (or its predecessor Monsanto Co.), 2) has been extracted from the scientific literature either as primary references or as found in well-accepted, peer-reviewed reference books, or 3) were estimated using environmental models accepted by the US EPA (1999b) for such purposes. This assessment includes information on physicochemical properties, environmental fate, and human and environmental effects associated with Partially Hydrogenated Terphenyls. The data used to support this program include those Endpoints identified by the US EPA (1998); key studies have been identified for each data Endpoint and summarized in Robust Summary form and included in Section VI. of this Dossier.

All studies were reviewed and assessed for reliability according to standards specified by Klimisch *et al* (1997), as recommended by the US EPA (1999a). The following criteria were used for codification:

1. Reliable without Restriction - Includes studies which comply with US EPA and/or OECD-accepted testing guidelines, which were conducted using Good Laboratory Practices (GLPs) and for which test parameters are complete and well documented,
2. Reliable with Restrictions – Includes studies which were conducted according to national/international testing guidance and are well documented. May include studies conducted prior to establishment of testing standards or GLPs but meet the test parameters and data

documentation of subsequent guidance; also includes studies with test parameters which are well documented and scientifically valid but vary slightly from current testing guidance. Also included were physical-chemical property data obtained from reference handbooks as well as environmental endpoint values obtained from an accepted method of estimation (i.e. EPISUITE).

3. Not Reliable – Includes studies in which there are interferences in either the study design or results that provide scientific uncertainty or where documentation is insufficient.

Those studies receiving a Klimisch rating of 1 or 2 are considered adequate to support data assessment needs in this Dossier.

III. TEST PLAN SUMMARY AND CONCLUSIONS

Conclusion: All HPV Endpoints have been satisfied with data from studies that were either well documented, used OECD guideline methods and conducted in accord with GLPs, or were estimated from acceptable estimation modeling programs. Hence, no further testing for any of the HPV Endpoints is deemed necessary, as summarized in Table 1.

In summary:

Physical-chemical property values (Melting Point, Boiling Point, Vapor Pressure, Partition Coefficient and Water Solubility) are measured values which have come from acceptable studies which were classified as “2-Reliable with restrictions”.

Environmental Fate values for Transport (Fugacity) were obtained for a significant representative component of the UVCB mixture using a computer estimation –modeling program (EPISUITE, 2002) recommended by EPA; as such, they were designated “2-Reliable with restrictions”. The EPISUITE program was unable to estimate Stability in Water (Hydrolysis). Based on the lack of functional groups suggestive of the potential for hydrolysis to occur, it is accepted that Partially Hydrogenated Terphenyls do not hydrolyze appreciably in an aqueous environment. Thus, no additional testing is needed for further confirmation. Biodegradation testing (SCAS and River Die-away) of Partially Hydrogenated Terphenyls has been conducted. The SCAS study was well-documented and was conducted using methodology that preceded, but is considered consistent with, methodology recommended in OECD test guideline 302. It, thus, has been designated as “2-Reliable with restrictions”. The River Die-Away study has been included as Supplemental information. Photodegradation of Partially Hydrogenated Terphenyls has been measured and documented within an internal study coded as “2-Reliable with restrictions”. Atmospheric half-life is estimated as 4.1 hours by the APOWIN program.

Ecotoxicity –Acute Fish, Plant (Algal) and Invertebrate Toxicity studies, consistent with OECD test guidance, have been designated as either “1-Reliable without restriction” or

“2-Reliable with restrictions”. Additional Supplemental studies have also been summarized for Acute Fish and Invertebrate Endpoints.

Mammalian Toxicity Endpoints (Acute Toxicity, Repeated Dose Toxicity, Ames and Chromosomal Aberration Testing, and Reproductive Toxicity) have all been filled with tests that either conformed directly with OECD test guidance or followed test designs similar to OECD guidance.

The Acute Toxicity Endpoint is supported by an oral rat toxicity study that was conducted according to OECD and GLP guidance and is considered “1- Reliable without restriction”.

The Repeated Dose Toxicity Endpoint has been met with a 90-Day Subchronic rat study conducted according to OECD guideline 408 and in accordance with GLPs. It has been codified as “1- Reliable without restriction”.

An Ames test, limited by conduct of a single rather than double trial, has been used to fulfill this HPV Endpoint. This study, published in a peer-reviewed journal, is considered “2-Reliable with restrictions”. In support of that study and its results, we also provide a similar Ames test, conducted internally according to OECD/GLP guidance with 4 of the 5 *Salmonella* tester strains called for in OECD study design, as Supplemental information.

An *in vivo* Chromosomal Aberration assay has been used to support its respective Endpoint. Following a study design equivalent to OECD guideline # 475, it has been classified as “1- Reliable without restriction”.

The Reproductive Toxicity HPV Endpoint has been filled using a Two-Generation Rat Reproduction study that generally followed OECD test guideline #416 and is considered “2- Reliable with restrictions”.

The Developmental Toxicity HPV Endpoint has been filled using an OECD 414 guideline compliant developmental toxicity study in rats. The study is well documented and considered to be of high reliability classified as “1-Reliable without restriction”.

Following is a tabular summary of the Test Plan developed for Partially Hydrogenated Terphenyls.

Table 1. Test Plan Matrix for Partially Hydrogenated Terphenyls

	Information Available?	OECD	GLP	Other Study	Estimation. Method	Acceptable?	Testing Recommended?
PHYSICAL CHEMICAL ENDPOINTS							
Melting Point	Y	N	N	N	-	Y	N
Boiling Point	Y	N	N	N	-	Y	N
Vapor Pressure	Y	N	N	N	-	Y	N
Partition Coefficient	Y	N	N	N	-	Y	N
Water Solubility	Y	Y	N	N	-	Y	N
ENVIRONMENTAL FATE ENDPOINTS							
Photodegradation	Y	N	N	N	Y/N	Y	N
Stability in Water	N	-	-	-	Y	Y	N
Biodegradation	Y	N	N	Y	-	Y	N
Transport between Environmental Compartments (Fugacity)	Y	N	N	N	Y	Y	N
ECOTOXICITY ENDPOINTS							
Acute Toxicity to Fish	Y	N	Y	Y	-	Y	N
Acute Toxicity to Aquatic Invertebrates	Y	Y	Y	Y	-	Y	N
Toxicity to Aquatic Plants	Y	N	N	N	-	Y	N
MAMMALIAN TOXICITY ENDPOINTS							
Acute Toxicity	Y	Y	Y	Y	-	Y	N
Repeated Dose Toxicity	Y	Y	Y	N	-	Y	N
Genetic Toxicity – Mutation (Ames)	Y	Y	Y	Y	-	Y	N
Genetic Toxicity – Chromosomal Aberrations	Y	Y	Y	N	-	Y	N
Developmental Toxicity	Y-	Y-	Y-	Y-	N	Y	N
Reproductive Toxicity	Y	Y	Y	N	-	Y	N

Y = Yes; N = No; - = Not applicable

IV. DATA SET SUMMARY AND EVALUATION

The key studies used in this assessment to fulfill the HPV requirements have been placed in an Endpoint-specific matrix, and further discussed below. Robust Summaries for each study referenced can be found in Section VI of this Dossier.

A. Chemical/Physical Properties

Table 2. Selected Chemical/Physical Properties of Partially Hydrogenated Terphenyls

Chemical	Boiling Pt. (°C.)	Melting Pt.(° C.)	Vapor Pressure (hPa @ 25 °C)	Water Solubility (mg/L)	Partition Coefficient (Log Kow)
Partially Hydrogenated Terphenyls CAS No. 61788-32-7	359	-32 (pour point)	0.002666	< 0.06	6.13

All HPV Endpoints for Physical-Chemical Properties have been completed with reliable information, either taken from studies that have been designated as “2-Reliable with restrictions”, are included in the Robust Summary section of this Dossier.

In summary, these data indicate that Partially Hydrogenated Terphenyls is a liquid at room temperature and has a very low vapor pressure. It has a moderately high octanol:water partition coefficient and very low solubility in water.

Conclusion – Adequate reference values are available to provide needed information on the Physical-Chemical Properties associated with Partially Hydrogenated Terphenyls. Therefore, no additional data development is needed for these HPV Endpoints.

B. Environmental Fate and Biodegradation

Both a Semi-Continuous Activated Sludge (SCAS) test and a River Die-Away test have been conducted with Partially Hydrogenated Terphenyls. While conducted prior to inception of standardized international guidelines for **Biodegradability** testing and GLPs, these studies followed similar standards for conduct subsequently codified into OECD guideline 302 and GLP documentation. They are considered “2-Reliable with restrictions”. Both studies have been summarized in the Robust Summary section of this Dossier. The SCAS study has been selected to fulfill this HPV Endpoint and is cited in Table 3 below.

No/little information could be located regarding Stability in Water (Hydrolysis) and Transport (Fugacity) for Partially Hydrogenated Terphenyls following an extensive literature search. We have incorporated the use of the estimation models found in EPISUITE (2002) for determination of **Fugacity** for a major component (1,3-dicyclohexyl benzene) of Partially Hydrogenated Terphenyls (PHT)s, as PHTs is a UVCB substance without a defined structure. The values derived are cited with the Robust Summaries and also are included in Table 3 and has been judged as “2-Reliable with restrictions”. No Hydrolysis values could be calculated using EPISUITE (2002) for either the mixture or a major component (dicyclohexyl benzene), as these chemicals have only saturated/unsaturated aromatic rings and no functional groups. These structures are consistent with those listed in Lyman et al, 1990) as “Generally Resistant to Hydrolysis”. Thus, “[t]esting for Stability in Water is not needed for substances generally recognized to have molecular structures or possess only functional groups that are generally known to be resistant to hydrolysis” (OECD, 2002). In addition, a technical discussion, based on thermodynamic principles, is included in the robust summary that provides the chemical rationale for the water stability of this material.

Table 3. Environmental Fate and Biodegradation Parameters for Partially Hydrogenated Terphenyls

Chemical	Biodegradation Rate	Stability in Water (T _{1/2} days @ 25 deg.)	Fugacity (%)	Photodegradation Rate (T _{1/2})
Partially Hydrogenated Terphenyls CAS No. 61788-32-7	35 %	Not susceptible to Hydrolysis	Air – 0.2 Water – 3.6 Soil – 27.5 Sediment – 68.7	Direct 86 days Indirect 4.1 hours

The Environmental Fate and Biodegradability of Partially Hydrogenated Terphenyls can be summarized as follows.

Partially Hydrogenated Terphenyls would not be expected to normally enter the aquatic environment, as they are intended to be used in enclosed systems. However, their limited entry could be envisioned after incidental spills and equipment leakage. Thus, based on Fugacity modeling, their environmental fate is expected to focus on the soil and sediment as main environmental target compartments. As Partially Hydrogenated Terphenyls are not readily hydrolysable, have exceedingly low water solubility characteristics and appear to undergo limited photolysis, their presence in aqueous or atmospheric compartments is minimal. Partially Hydrogenated Terphenyls can be expected to partition mostly to the soil or sediment. As part of the soil or sediment, Partially Hydrogenated Terphenyls will degrade; while not Readily Biodegradable, biodegradation has been established in inherent biodegradation studies (SCAS and River Die Away). The results of these tests support the conclusion that the test substance will eventually biodegrade.

Conclusion – Adequate studies are available to provide needed information for the HPV Designated Environmental Properties associated with Partially Hydrogenated Terphenyls. No further testing is planned.

C. Aquatic Toxicity

Sufficient information is available to characterize the acute toxicity of Partially Hydrogenated Terphenyls to algae, invertebrates and fish. An acute fish study, following OECD test guidance has been conducted on F. Minnows and is considered “2-Reliable with restrictions”. A similar study with R. trout has been provided as Supplemental information. A Robust Summary has been prepared for these studies and the F. Minnow study cited in Table 4.

A well-conducted study summarizing the effects of Partially Hydrogenated Terphenyls in *D. magna* and has been used to fulfill the Acute Invertebrate Toxicity Endpoint. It has been judged as “1-Reliable without restriction”.

An acute Algal study fulfills the Acute Plant Toxicity HPV Endpoint. While not conducted specifically to meet OECD guidelines, this study used methodology recommended by the US EPA Committee of Methods for Toxicity Testing with Aquatic Organisms (EPA, 1975). These recommendations are consistent with OECD guidelines. Hence, it has been designated as “2- Reliable with restrictions”, selected for development of Robust Summaries, and is cited in Table 4.

Several of the acute aquatic studies referenced above used nominal test levels which exceeded the very low (<0.06 ppm) water solubility limit for Partially Hydrogenated Terphenyls. In review of the study data, no treatment-related toxicity was discernable at test levels which clearly exceeded solubility limits. Thus, it is scientifically rational to conclude that the EC50/LC50 for Partially Hydrogenated Terphenyls is in excess of this aqueous solubility limit. Further efforts to derive a toxicity value above the solubility limits of this substance would provide no meaningful value useful in the assessment of environmental risk.

Table 4. Aquatic toxicity parameters for Partially Hydrogenated Terphenyls

Chemical	Fish LC 50 (mg/L)	Invertebrate EC50 (mg/L)	Algae EC50 (mg/L)
Partially Hydrogenated Terphenyls CAS No. 61788-32-7	> 0.06 (limit of solubility)	>1.34	> 0.06 (limit of solubility)

Conclusion – An adequate study is available to meet each of the three Acute Aquatic Toxicity Endpoints for Partially Hydrogenated Terphenyls. No additional testing is necessary for this completed HPV Endpoint category.

D. Mammalian Toxicity

A summary of toxicity data used to fulfill the HPV Endpoints for Mammalian Toxicity is found in Table 5. Each report citation has been further summarized in the Robust Summary section of this Dossier.

Table 5. Mammalian Toxicity of Partially Hydrogenated Terphenyls

HPV Endpoint	Result
Acute Oral	LD50 > 10,000 mg/kg (rat)
Repeated-dose Toxicity	91-Day Rat Oral NOEL = 200 ppm
Ames Test	Non-mutagenic: TA 1535, 1537, 1538, 98, 100 with and w/out S9
Chromosomal Aberrations	in vivo rat bone marrow test: not genotoxic
Reproductive Toxicity	2-Generation Rat: Reproductive NOAEL = 1000 ppm Systemic NOAEL = 300 ppm
Developmental Toxicity	Rats OECD 414 days 6-15 of gestation Maternal and Developmental NOAEL = 500 mg/kg Maternal and Developmental LOAEL = 1500 mg/kg

1.0 Acute Toxicity

Results of an acute oral toxicity study with Partially Hydrogenated Terphenyls fulfill the HPV Acute Toxicity Endpoint. This study was conducted as a Limit Test according to OECD Test Guidelines and GLP guidance and provides sufficiently reliable, documented information to be classified as “1- Reliable without restriction”.

Thus, Partially Hydrogenated Terphenyls is considered to be practically non-toxic after administration by acute oral dosing.

Conclusion – A study of sufficient quality is available to assess the Acute hazard associated with Partially Hydrogenated Terphenyls. Therefore, no additional data development is needed for the Acute Toxicity HPV Endpoint.

2.0 Repeated Dose Toxicity

Partially Hydrogenated Terphenyls has been adequately tested in a subchronic rodent study to define its Repeated Dose toxicity. This study is cited in Table 5 and summarizes a 91-day subchronic rat study by the oral route. This study was conducted using a study design according to OECD Test Guideline 408, and conducted under GLP auspices.

Hence, it is considered “1- Reliable without restriction”. In all cases, no evidence of an effect on the male or female reproductive organs (including testes) was observed.

Conclusion - The Repeated Dose HPV Endpoint for Partially Hydrogenated Terphenyls has been fulfilled with a well-conducted and documented 90-Day Subchronic study in rats deemed “1- Reliable without restriction”. No further testing is needed for completion of information related to the Repeat Dose HPV Endpoint.

3.0 Mutagenicity and Chromosomal Aberrations

3.1 Ames/Point Mutation Testing

When tested in two standard Ames assays for point mutations, Partially Hydrogenated Terphenyls elicited no mutagenic response in any of the *S. Typhimurium* tester strains employed, either with or without inclusion of metabolic activation (Table 5). The published, peer-reviewed literature study (Clark et al., 1979) has been classified as “2- Reliable with restrictions” due to its use of fewer replications than recommended in OECD study guide # 471. However, an additional, well-documented Ames assay (Solutia study no. DA-78-184-see Robust Summary), conducted internally with 4 of the 5 *Salmonella* tester strains included in the OECD test guidance, validates the conclusion of a lack of mutagenicity reported in the literature with Partially Hydrogenated Terphenyls. Both studies are summarized in the Robust Summary section of this Dossier.

Thus, it is concluded that adequate testing of sufficient quality has been performed on Partially Hydrogenated Terphenyls to evaluate the Ames Test (Point Mutation) HPV requirement; no further testing is needed for this Endpoint.

3.2 - Chromosomal Aberrations

Partially Hydrogenated Terphenyls has been tested *in vivo* for induction of Chromosomal Aberrations in rat bone marrow cells. This study followed OECD Guideline # 475 and was conducted following GLPs. Thus this study is considered as “1-Reliable without restriction”. No mutagenic activity was observed.

The HPV Chromosomal Aberration Endpoint for testing of Partially Hydrogenated Terphenyls has, thus, been fulfilled with an adequately conducted and documented *in vivo* study; no further testing is needed.

4.0 Reproductive Toxicity

Of direct relevance to completion of the Reproductive Toxicity Endpoint for this HPV assessment with Partially Hydrogenated Terphenyls, is identification of a well documented 2-Generation rat Reproduction Toxicity study conducted in general accord with OECD Guideline 416. This study has been assessed as “2- Reliable with

restrictions”. It has been summarized in the Robust Summary section of this Dossier and is included in Table 5.

No evidence of reproductive toxicity was observed in this study nor were morphological effects of either male or female reproductive organs observed in this study or following subchronic testing (Table 5).

In conclusion, the Reproductive Toxicity HPV Endpoint has been fulfilled using a well documented and conducted 2-Generation Reproductive study which has been assessed as “2- Reliable with restrictions”. Thus, the data requirements for this HPV Endpoint have been met and no further testing is required.

5.0 Developmental Toxicity

An OECD-414 guideline developmental toxicity study has been conducted with Partially Hydrogenated Terphenyls. This GLP study is well documented and has been assigned as “1-Reliable without restrictions”. It has been summarized in the Robust Summary section of this Dossier and is included in Table 5.

Mild developmental toxicity was observed at the maternally toxic dose of 1500 mg/kg-day. Both the developmental and maternal NOAEL is considered 500 mg/kg-day and it is concluded that this material is not a specific developmental toxin. Furthermore, the dose level associated with mild developmental toxicity is very high suggesting little or no risk to man.

V. REFERENCES

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VI. ROBUST STUDY SUMMARIES -

An IUCLID Data Set for Hydrogenated Terphenyls is Appended